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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/568,998	SFEIR ET AL.				
Office Action Summary	Examiner	Art Unit				
	Anoop Singh	1632				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
Responsive to communication(s) filed on This action is FINAL. 2b)⊠ This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro					
Disposition of Claims						
4) ☐ Claim(s) 1-98 is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) 1-98 are subject to restriction and/or expressions.	vn from consideration.					
Application Papers	-					
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acce Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	epted or b) objected to by the I drawing(s) be held in abeyance. See ion is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate				

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DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-3, 41-42, 54-55, drawn to method of inducing biomineralization, Bone, periodontal regeneration in a tissue, which method comprises administering to the tissue a Phosphophoryn (PP) protein having or comprising SEQ ID NO: 1 or fragment thereof in an amount sufficient to induce biomineralization, bone, periodontal regeneration in a tissue, classified in class 514, subclass 2.
- II. Claims 4-7, 17-20, 43-46 and 56-59, drawn to drawn to method of inducing biomineralization, Bone, periodontal regeneration in a tissue, which method comprises administering to the tissue a nucleic acid molecule encoding Phosphophoryn (PP) protein, a fragment of derivative in an amount sufficient to induce biomineralization, bone, periodontal regeneration in a tissue, classified in class 514, subclass 44.
- III. Claims 26, 27, drawn to a method of inducing differentiation of a cell into an osteogenic cell or an odontogenic cell, which method comprises administering to the cell a PP protein in an amount sufficient to induce differentiation of the cell into an osteogenic cell or an odontogenic cell, classified in class 424, subclass 198.1.
- IV. Claims 28-31, drawn to drawn to a method of inducing differentiation of a cell into an osteogenic cell or an odontogenic cell, which method comprises administering to the cell a nucleic acid encoding PP protein in an amount sufficient to induce differentiation of the cell into an osteogenic cell or an odontogenic cell, classified in class 435, subclass 325.

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- V. Claims 67-68, drawn to method of inducing differentiation of a cell into a cementoblast, osteoblast, or periodontal ligament cell, which method comprises administering to the cell or a periodontal space a source of PP protein in an amount sufficient to induce differentiation of the cell into a cementoblast, osteoblast, or periodontal ligament, classified in class 424, subclass 198.1.
- VI. Claims 69-72, drawn to method of inducing differentiation of a cell into a cementoblast, osteoblast, or periodontal ligament cell, which method comprises administering to the cell or a periodontal space a source of nucleic acid encoding PP in an amount sufficient to induce differentiation of the cell into a cementoblast, osteoblast, or periodontal ligament, classified in class 435, subclass 325.
- VII. Claims 85-86, drawn to a composition of comprising PP protein, a fragment or derivative thereof, classified in class 514, 530, subclass 7, 352.
- VIII. Claims 87-89, drawn to a composition of comprising nucleic acid encoding PP protein, a fragment or derivative thereof, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons: Linking Claims:

Claims 1, 8-14, 21-24, 40, 47-53, 60-63 and 64 link inventions of group I-II. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims 1, 8-14, 21-24, 40, 47-53, 60-64. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking

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claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 25, 32-38 and 39 link inventions of group III-IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims 25, 32-38 and 39. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 66, 73-80 and 81 link inventions of group V-VI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims 66, 73-80 and 81. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may

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be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 83-84, 90-97 and 98 link inventions of group VII-VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims 83-84, 90-97 and 98. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I, III, V and II, IV, VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions of groups I, III, V and II, IV, VI are patentably distinct, each from other because they are drawn to methods that have distinct step and use material compositions that have distinct structure, function and utility. For example, the method of groups I, III, V require administering a polypeptide, while the method of groups II, IV, VI require administering nucleic acid encoding PP. The route and mode of administration of protein will be distinct and different as compared to groups involving nucleic acid. Furthermore, the a composition of PP protein in groups I, III, V would have distinct and different physical and chemical

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structure as compared to nucleic acid encoding PP of groups II, IV, VI. Therefore, these distinct compositions in the method would require separate searches in commercial data bases. In addition, the invention of groups I, III, V and II, IV, VI have a separate status in the art as shown by their different classifications. Therefore, searches for these inventions will not be coextensive in the patent and non-patent literature.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions of groups I and III are patentably distinct, each from other because they are drawn to methods that have distinct step and use material compositions that have distinct structure, function and utility. For example, the method of group I requires administering a polypeptide to induce bone, while the method of group III require inducing differentiation of a cell into an osteogenic cell or an odontogenic cell. The method of inducing differentiation of cell could be accomplished under *in vitro* condition by growing cells in presence of PP and other growth factor, while method of group I require administering PP to a tissue intended for the induction of bone or pulp formation. Therefore, searching for different method steps for these inventions will not be coextensive in the patent and non-patent literature.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions of groups I and V are patentably distinct, each from other because they are drawn to methods that have distinct step and use material compositions that have distinct structure, function and utility. For example, the method of group I requires administering a polypeptide to induce bone, while the method of group V requires inducing differentiation of a cell into cementoblast,

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osteoblast, or periodontal ligament cell. The method of inducing differentiation of cell could be accomplished under *in vitro* condition by growing cells in presence of PP protein and other growth factor, while method of group I requires administering PP to a tissue intended for the induction of bone or pulp formation. Therefore, searching for different method steps for these inventions will not be coextensive in the patent and non-patent literature.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions of groups II and IV are patentably distinct, each from other because they are drawn to methods that have distinct step and use material compositions that have distinct structure, function and utility. For example, the method of group II requires administering a nculeic acid encoding a polypeptide to induce bone, while the method of group IV requires inducing differentiation of a cell into an osteogenic cell or an odontogenic cell by transfecting the nucleic acid of the invention. The method of inducing differentiation of cell could be accomplished under *in vitro* condition by growing cells in presence of nculeic acid encoding PP and other growth factor, while method of group II requires administering via specific route a nucleic acid PP to the tissue intended for the induction of bone or pulp formation. Therefore, searching for different method steps for these inventions will not be coextensive in the patent and non-patent literature.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions of groups II and VI are patentably distinct, each from other because they are drawn to methods that have distinct step and use material compositions that have distinct structure, function and utility. For example, the method of group II requires administering a nucleic acid encoding a polypeptide to

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induce bone, while the method of group VI requires inducing differentiation of a cell into cementoblast, osteoblast, or periodontal ligament cell. The method of inducing differentiation of cell could be accomplished under *in vitro* condition by growing cells in presence of a nucleic acid encoding PP protein and other growth factor, while method of group II requires administering nucleic acid encoding PP to a tissue intended for the induction of bone or pulp formation. Therefore, searching for different method steps for these inventions will not be coextensive in the patent and non-patent literature.

Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions of groups VII and VIII are patentably distinct, each from other because they are drawn to composition that have distinct structure, function and utility. For example, the method of group VII requires protein, while composition of group VIII requires nucleic acid. Each composition has distinct and different physical and chemical structure that would require separate sequence search. Therefore, searching composition comprising protein will not be coextensive with composition comprising nucleic acid in the patent and non-patent literature.

Inventions VII and I, III V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case PP protein could be used to generate antibody or make diagnostic kit.

Inventions VIII and II, IV, VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a

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materially different process of using that product. See MPEP § 806.05(h). In the instant case nucleic acid encoding PP could be used in gene expression analysis or making diagnostic probe. Thus, groups VIII and II, IV, VI are related as product and process of use and therefore, they require non-coextensive searches in the patent and non non-patent literature.

A search and examination of more than one invention as defined above would unduly burden the office. Each of the invention requires a different search of the art and concerns separate consideration of patentability. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is

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advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of species

1. This application contains claims directed to the following patentably distinct species of selected from osteogenic factor or the growth factor is a Bone Morphogenic Protein (BMP), Latent Membrane Protein-3 (LMP-3), a Platelet-Derived Growth Factor (PDGF), an Insulin Growth Factor (IGF), a Vascular Endothelial Growth Factor (VEGF), RunX, Osterix (Osx), or a Fibroblast Growth Factor (FGF). The species are distinct because each growth factor has a distinct structure and have different mode of action that would require separate search in commercial patent, non patent literature and sequence databases. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 10, 22, 37, 49, 63, 79 and 91 are generic.

2. This application contains claims directed to the following patentably distinct species of selected from PP formulation that is in a toothpaste, an oral rinse, a chewing gum, a dissolvable tablet, a dissolvable film, a gel, a natural biodegradable polymer, a synthetic biodegradable polymer, or a non-biodegradable polymer. The species are distinct because each formulation require distinct and different composition, have different mode of action and that would require

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separate search in commercial patent, non patent literature and sequence databases. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 25, 40, 52, 66, 84 are generic.

3. This application contains claims directed to the following patentably distinct species of selected from PP formulation that is in a toothpaste, an oral rinse, a chewing gum, a dissolvable tablet, a dissolvable film, a gel, a natural biodegradable polymer, a synthetic biodegradable polymer, or a non-biodegradable polymer, optionally in combination with a calcium phosphate. The species are distinct because each formulation require distinct and different composition, that has different disintegration rate that would require separate search in commercial patent, non patent literature and sequence databases. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 14 is generic.

4. This application contains claims directed to the following patentably distinct species of selected from biodegradable polymer, a biocompatible ceramic, or a combination thereof. The species are distinct because each polymer and ceramic has different physical and chemical structure that would require separate search in commercial patent, non patent literature and sequence databases. The species are independent or distinct because claims to the different species recite the mutually

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exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 83 is generic.

5. This application contains claims directed to the following patentably distinct species of selected from water soluble polymer is polyethylene glycol, agarose, or alginate. The species are distinct because each water soluble polymer has different physical and chemical structure that would require separate search in commercial patent, non patent literature and sequence databases. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 93 is generic.

6. This application contains claims directed to the following patentably distinct species of selected from non-water soluble polymer is polycaprolactone (PCL), polylactide (PLA), polyglycolic acid-lactic acid (PGLA), or a combination thereof. The species are distinct because each water non soluble polymer has different physical and chemical structure that would require separate search in commercial patent, non patent literature and sequence databases. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 93 is generic.

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7. This application contains claims directed to the following patentably distinct species of selected from the group consisting of hydroxyapatite, substituted brushite, unsubstituted brushite, substituted tricalcium phosphate (TCP), unsubstituted TCP, amorphous calcium phosphate (ACP), or a combination thereof. The species are distinct because each ceramics has different physical and chemical structure that would require separate search in commercial patent, non patent literature and sequence databases. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 92 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i). Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anoop Singh AU 1632

/Thaian N. Ton/ **Primary Examiner**Art Unit 1632